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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,573	04/06/1999	DAVID R. WALT	A-67207-2/DJB/RMS/DCF	6459

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/287,573	WALT ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-27 and 29-48* is/are pending in the application.

4a) Of the above claim(s) *16-19,23-26,40-45 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22, 27, 29-39, 46, and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-27 and 29-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed April 4, 2005 is acknowledged and has been entered. Claims 20, 27, 29-30, and 32-33 have been amended. Claim 28 has been cancelled. Claims 16-19, 23-26, 40-45, and 48 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 16-27 and 29-48 are pending. Claims 20-22, 27, 29-39, 46, and 47 are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

3. The rejections of claim 28 are now moot in light of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20-22, 27, 29-39, 46, and 47 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 remains indefinite in failing to clearly define essential structural and functional cooperative relationships between elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear how the claimed identical sensor elements having the same bioactive agent within each subpopulation in the array structurally and functionally relate to a first target analyte to which the array is contacted, in order to thereby produce a response signal. For example, does the bioactive agent have specificity or affinity towards the first target analyte so that there is binding therebetween that causes production of a response signal at the sensor elements; or does the bioactive agent interact with the target analyte which causes production of a response signal at the sensor elements. As recited, it appears that a response signal will always be produced from the sensor elements by virtue of just contacting with a target analyte, regardless of whether the bioactive agents are the same. Accordingly, it is unclear how this instant method is one that performs statistical analysis and measurements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 27, 29-39, and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196) in view of Bierre et al. (US Patent 5,739,000) for reasons of record.

6. Claims 20, 22, and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196) in view of in view of Bierre et al. (US Patent 5,739,000), as applied to claims 27, 29-39 and 47 above, and in further view of Stimpson et al. (US Patent 5,559,668) for reasons of record.

7. Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196) in view of Bierre et al. (US Patent 5,739,000), as applied to claims 27, 29-39 and 47 above, and in further view of Stimpson et al. (US Patent 5,559,668) and Sadana et al. (Sensors and Actuators B-Chemical, 32 (3): 195-201) for reasons of record.

Response to Arguments

8. Applicant's arguments filed April 4, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that the teaching of Bierre cannot be combined with the teaching of Pinkle because Bierre teaches non-analogous art, i.e. hierarchical collection of single parameters at a time in the method of Bierre as opposed to multiparameter data collection in the method of Pinkle; hence, Bierre teaches away from the claimed invention and as such the proposed combination is rendered inoperable and there would have been no motivation or suggestion to combine the two references to arrive to

the teaching of the claimed invention. Applicant specifically contends that the further combination of Stimpson and/or Sadana with Pinkle and Bierre, do not render obvious the instant invention because neither Stimpson nor Sadana cure the deficiencies of the combination of Pinkle with Bierre.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In as far as Applicant's argument that Bierre's teaching is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Pinkel discloses a method of simultaneous measurement of target analytes wherein an optical fiber array having a plurality of subpopulations of identical sensor elements in optical fibers bundled together bearing a single type species, is provided and contacted with a sample comprising target analytes. A detector is arranged to read signals, obtain simultaneous measurements from a single sensor element of the optical fiber or from a group of sensor elements from a population or bundle of optical fibers, and equipped with a computerized data acquisition system and analytical program to enable a variety of different measurements to be made under diverse parameters. By examining the uniquely addressed transmission ends of fibers

or groups of fibers, the addressed transmission ends can transmit unique patterns for rapid identification and measurement of analytes by the sensor. Bierre is incorporated herein, only for teaching statistical analysis of data from measurements obtained such as mean, and standard deviations, validity of measurements, i.e. defining and selecting particles into mutually exclusive clusters and subclusters (cluster analysis), and repeating statistical analysis for optimization purposes and comparing and evaluating confidence intervals between measurements. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of statistical analysis in the method of Bierre into the method of Pinkel because statistical analysis, is conventional and standard laboratory practice required for optimization procedures. Accordingly, the rejection of claims 20-22, 27, 29-39, 46, and 47 as being unpatentable over Pinkle in view of Bierre, and also further in view of Stimpson and Sadana, are being maintained for reasons of record.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

9. For reasons aforementioned, no claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
June 9, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/13/05